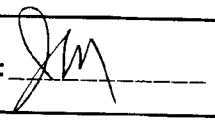
I. PREANALYTICAL EVENTS

Approved: 

Clinical Laboratory Medicine
078 - PEDIATRIC CYTOGENETICS LABORATORY

			TECHNICAL CHARGE
078	0005	Amniotic Fluid or Tissue Culture and Chromosomal Analysis	$788.00
078	0002	Blood Chromosomal Analysis	$451.00
078	0006	Cell Culture (Amniotic Fluid or Tissue)	$384.00
078	0007	Bone Marrow Chromosomal Analysis	$772.00
078	0008	Blood Chromosomal Analysis of Additional Family Member	$385.00

Chromosome Anyalysis for Breakage studies-Score 100 cells

Chromosome Analysis; Count additional 50 cells for Mosaicism

Chromosome Analysis for Fragile X

Chromosome Analysis, additional Karyotyping

Specialized Banding Techniques (C, NOR, Q etc.)

In Situ Hybridization for Microdeletions

Chromosome Analysis, Additional High Resolution

Approved: _____

AMNIOTIC FLUID FOR PRENATAL DIAGNOSIS

1.Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465).

2.20-30 cc of amniotic fluid (obtained at 16 weeks post-LMP or 14 weeks post-conception) should be drawn aseptically into a syringe after discarding the first 1-2 cc of fluid. The sample can be delivered in the same syringe capped tightly with a sterile cap, or the sample can be transferred to a sterile tube and capped tightly. Label the sample with the patient's name and date of birth.

3.Complete the Amniotic Fluid Study Request Form (see attached). These will be available in the Private OB Clinic and the Non-Stress Room. Label 3 consult sheets and a Pediatric Cytogenetics Laboratory charge slip.

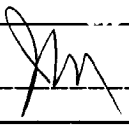
4. a. UTMB Patient: Sample should be submitted to the laboratory as soon as possible at room temperature packaged well to prevent breakage or leakage.
   b. Off-Campus Patient: Delivery must be within 24 hours of the tap or growth of the cells may be seriously jeopardized.

5.Samples should be delivered to the Pediatric Cytogenetics Laboratory, Suite 3.350, Children's Hospital, in the University of Texas Medical Branch Complex, Galveston, Texas 77555-0359.

6.Preliminary results will be available in 14-18 days. A final written report will be sent in 3-4 weeks. Physician will be notified by day 7 if there are anticipated delays.

7. Confirmation of an abnormal amniotic fluid sample result is confirmed through concurrent fetal PUBS blood or subsequent post-mortem skin fibroblast chromosome testing.

Any questions should be directed to either Jerome McCombs, Ph.D., or Lillian H. Lockhart, M.D. at 409/772-3466 or 409/772-3465.

Approved: 

We are in a transitional phase. We have changed our charge slip to reflect the services that we are providing.

The following are examples of how the charge slips should be completed:

1. Stamp or generate charge sticker. This will contain name, UH #, DOB and billing information
2. Check test(s) to be ordered
3. Requesting Faculty
4. Collection Time and Date
5. Receipt time and Date to be added by receiving technologist
6. **It is the responsibility of the technologist receiving the sample to verify the information for completeness and that the paperwork matches the sample.**
7. **Discrepancies are to be recorded in the exceptional case records and reported to the Laboratory Director as soon as possible.**
8. **Inappropriate or incomplete paperwork could be grounds for refusing a sample.**
9. The orginal copy is retained in the file.
10. The yellow copy is used for laboratory billing and then forwarded to the billing office for professional reimbursement.
11. The new bill provides sample collection and delivery information.
12. Oral request for studies must be followed w/ the appropriate consult sheet and clinical information. Information should be received within 30 days.

CYTOGENETICS REQUEST FORM

REQUEST FORM TO BE ACCOMPANIED BY TWO STAMPED CONSULT SHEETS.

	BLOOD CHROMOSOME ANALYSIS 5-10MLS OF SODIUM HEPARINIZED BLOOD
	AMNIOTIC FLUID OR TISSUE CULTURE AND CHROMOSOME ANALYSIS 15-30CC AMNIOTIC FLUID - BY PRIOR ARRANGEMENT WITH LAB
	TISSUE CULTURE AMNIOTIC FLUID OR TISSUE CULTURE BY PRIOR ARRANGEMENT WITH LAB
	BONE MARROW CHROMOSOME ANALYSIS BY PRIOR ARRANGEMENT WITH LAB
	BLOOD CHROMOSOME ANALYSIS; ADDITIONAL FAMILY MEMBER BY PRIOR ARRANGEMENT WITH LAB
	TESTS BELOW MUST INCLUDE ONE OF THE ABOVE SERVICES
	CHROMOSOME ANYALYSIS FOR BREAKAGE STUDIES - SCORE 100 CELLS
	CHROMOSOME ANALYSIS; COUNT ADDITIONAL 50 CELLS FOR MOSAICISM
	CHROMOSOME ANALYSIS FOR FRAGILE X
	CHROMOSOME ANALYSIS, ADDITIONAL KARYOTYPING
	SPECIALIZED BANDING TECHNIQUES (C,NOR,Q etc.)
	IN SITU HYBRIDIZATION FOR MICRODELETIONS
	CHROMOSOME ANALYSIS, ADDITIONAL HIGH RESOLUTION

DELIVER TO: CYTOGENETICS LABORATORY
3.350 CHILDRENS HOSPITAL
EXTENSIONS: 23466 OR 23465

REQUESTING PHYSICIAN:	DIAGNOSIS: ICD-9 CODE:	COLLECTED BY: DATE/TIME:
Unit History #: Name: Financial #: Location:	**UNIVERSITY OF TEXAS MEDICAL BRANCH** **LABORATORY MEDICINE - GALVESTON, TX 77555-0743** **CLIA #45D0660281 CAP #21251-01** **MICHAEL BISSEL, M.D., Ph.d., M.P.H. - CLINICAL DIRECTOR** **ABIDA K. HAQUE, M.D. - ANATOMIC DIRECTOR** **TELEPHONE: (800) LAB 2266**	Results to Physician (Name and ID #): Floor/Clinic Phone Extension: UTMB Doctor #/Beeper #:

PLACE INVISION LABEL HERE

PLACE LIS LABEL HERE

CY 0001202

NAME: UH#: CY	NAME: UH#: CY 0001202	NAME: UH#: CY	NAME: UH#: CY 0001202

CYTOGENETICS REQUEST FORM

REQUEST FORM TO BE ACCOMPANIED BY TWO STAMPED CONSULT SHEETS.

	BLOOD CHROMOSOME ANALYSIS 5-10MLS OF SODIUM HEPARINIZED BLOOD
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	CHROMOSOME ANALYSIS, ADDITIONAL KARYOTYPING
	SPECIALIZED BANDING TECHNIQUES (C,NOR,Q etc.)
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PLACE INVISION LABEL HERE

PLACE LIS LABEL HERE

CY 3001202

Approved: [signature]

SAMPLE PRIORITY (Most to Least Crucial)

1. Percutaneous Blood Sampling (PUBS)*
2. Peripheral blood from newborn
3. Peripheral blood from pregnant couple
4. Amniotic fluid
   a. 20 week's gestation
   b. Less than 20 weeks
   c. More than 20 weeks
5. Bone marrow
6. Other peripheral blood samples
   a. Non-fragile(x), non-Fanconi's anemia
   b. Fragile(x)
   c. Fanconi's anemia
7. Skin fibroblasts
   a. Metabolic studies
   b. Autopsy specimens
8. Research samples

*PUBS are to be reported (preliminary) within 72 hrs with appropriate documentation in the chart. The written report is to be finalized within seven days.

* Any delay that can be anticipated that would

Approved: _____

AMNIOTIC FLUID FOR PRENATAL DIAGNOSIS

1.Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465).

2.20-30 cc of amniotic fluid (obtained at 16 weeks post-LMP or 14 weeks post-conception) should be drawn aseptically into a syringe after discarding the first 1-2 cc of fluid. The sample can be delivered in the same syringe capped tightly with a sterile cap, or the sample can be transferred to a sterile tube and capped tightly. Label the sample with the patient's name and date of birth.

3.Complete the Amniotic Fluid Study Request Form (see attached). These will be available in the Private OB Clinic and the Non-Stress Room. Label 3 consult sheets and a Pediatric Cytogenetics Laboratory charge slip.

4. a. UTMB Patient: Sample should be submitted to the laboratory as soon as possible at room temperature packaged well to prevent breakage or leakage.
   b. Off-Campus Patient: Delivery must be within 24 hours of the tap or growth of the cells may be seriously jeopardized.

5.Samples should be delivered to the Pediatric Cytogenetics Laboratory, Suite 3.350, Children's Hospital, in the University of Texas Medical Branch Complex, Galveston, Texas 77555-0359.

6.Preliminary results will be available in 14-18 days. A final written report will be sent in 3-4 weeks. Physician will be notified by day 7 if there are anticipated delays.

7. Confirmation of an abnormal amniotic fluid sample result is confirmed through concurrent fetal PUBS blood or subsequent post-mortem skin fibroblast chromosome testing.

Any questions should be directed to either Jerome McCombs, Ph.D., or Lillian H. Lockhart, M.D. at 409/772-3466 or 409/772-3465.

PEDIATRIC CYTOGENETICS LABORATORY
331 CHILDREN'S HOSPITAL, UTMB, GALVESTON, TEXAS 77555-0359
409/772-3465

AMNIOTIC FLUID STUDY REQUEST FORM

PLEASE DISCARD FIRST 1-2 CC OF AMNIOTIC FLUID

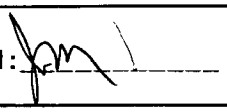
Date_____ Time_____ (Lab Use Only - Lab No_____)
Patient's Name _____ UH#:_____
Patient's Address_____
Patient's Phone _____Date of Birth _____ LNMP _____
Gestational Age: By ultrasound _____ When _____ By Dates____
Name of UTMB Physician Performing Amniocentesis_____
What is the reason for the amniocentesis?_____
_____
NAME AND ADDRESS OF OB SATELLITE CLINIC PATIENT ATTENDS_____
_____
_____
IF PRIVATE, NAME AND ADDRESS OF PRIVATE OBSTETRICIAN PATIENT ATTENDS _____
_____Telephone_____
DID YOU DISCARD THE FIRST 1-2 CC OF AMNIOTIC FLUID? Yes _____No_____
If not, why_____

LABORATORY USE ONLY

Number of syringes received _____
Color of fluid_____ Contaminated with blood? Yes ___ No __
Collected_____Received_____Culture initiated _____
Cell pellet description (RBC's, size of pellet, etc.)_____

Number of flasks/coverslips set up_____ Tissue culture medium/ antibiotics used _____

THIS FORM MUST BE COMPLETED AND SENT WITH EACH AMNIOTIC FLUID SPECIMEN RECEIVED BY THE PEDIATRIC CYTOGENETICS LABORATORY (CHARGE SLIP AND 3 LABELED CONSULTS ALSO)

Approved: 

PERIPHERAL BLOOD FOR CHROMOSOME STUDIES

1. Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465).

2. Blood must be heparinized and sterile. Either wet the inside of a syringe with sodium heparin (without preservatives) leaving 0.10 cc before drawing the blood (2.0-5.0 ml); mix well; label sample with patient's name and date of birth OR draw blood (2.0-5.0 ml) into a vacutainer containing sodium heparin (without preservatives); mix well, label sample with patient's name and date of birth.

3. a. UTMB Patient: Label 3 consult sheets and one Pediatric Cytogenetics Laboratory charge slip and provide appropriate information.
   b. Off-Campus Patient: Contact laboratory for more information.

4. Sample should be submitted to the laboratory as soon as possible at room temperature. If there is a delay in delivery (overnight or weekend), the sample may be placed in the refrigerator (but not near the freezer). Keep it cool but not frozen. If delivering the sample during the summer, avoid overheating. Placing the sample in a cup of water with a small amount of ice may be helpful.

5. Samples should be delivered to the Pediatric Cytogenetics Laboratory, Room 331, Children's Hospital, in the University of Texas Medical Branch Complex, Galveston, Texas 77555-0359.

6. Preliminary results will be available in 7-10 days. A final written report will be sent in 3-4 weeks.

7. Any questions should be directed to either Jerome McCombs, Ph.D. or Lillian H. Lockhart, M.D. at 409/772-3466 or 409/772-3465.

8. A copy of the Laboratory Survival Manual is available at all nursing stations. The sampling procedures therein are reviewed annuallly.

Approved: _____

BONE MARROW FOR CHROMOSOME STUDIES

1. Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465).

2. Collect 2-5 ml of aspirate into: Either a vacutainer with sodium heparin OR a sodium heparinized syringe. Label sample with patient's name and date of birth.

3. a. UTMB Patient: Label 3 consult sheets and one Pediatric Cytogenetics Laboratory charge slip and provide appropriate information.
   b. Off-Campus Patient: Contact laboratory for more information.

4. a. UTMB Patient: Call laboratory and technician will come to pick up the sample.
   b. Off-Campus Patient: Sample should be submitted to the laboratory as soon as possible at room temperature, packaged well to prevent breakage or leakage. Delivery must be within 24 hours of collection or quality of the specimen may be greatly diminished. Store in the refrigerator until the sample is shipped. Do not freeze.

5. Samples should be delivered to the Pediatric Cytogenetics Laboratory,Suite 3.350, Children's Hospital, in the University of Texas Medical Branch Complex, Galveston, Texas 77555-0359. We can also arrange to pick up the sample ourselves.

6. Preliminary results will be available in 7-10 days. A final written report will be sent in 3-4 weeks.

7. Any questions should be directed to either Jerome McCombs, Ph.D. or Lillian H. Lockhart, M.D., at 409/772-3466 or 409/772-3465.

Approved: [signature]

SKIN SAMPLE FOR CHROMOSOME STUDIES

1. Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465).

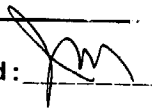
2. A roughly 4 mm^2 section of skin is taken from the deceased infant by the Cytogenetics technician using sterile techniques.

3. A consult sheet and Pediatric Cytogenetics charge slip are filled out by Autopsy Service.

4. The sample is returned to the Pediatric Cytogenetics Laboratory, Suite 3.350, Children's Hospital, UTMB, Galveston, Texas 77555-0359 and put to culture immediately.

5. Preliminary results will be available in roughly four weeks. A final written report will be sent in 5-6 weeks.

6. Any questions should be directed to either Jerome McCombs, Ph.D., or Lillian H. Lockhart, M.D., at 409/772-3466.

Approved: 

SKIN SAMPLE FOR METABOLIC STUDY

1. Schedule sample with the Pediatric Cytogenetics Laboratory (409/772-3465). Pick up a sterilized skin pack and test tube with growth medium from the Cytogenetics lab.

2. Using the skin punch in the skin pack, collect a skin sample. Label sample with patient's name and date of birth.

3. Submit sample to the Pediatric Cytogenetics Laboratory and return skin pack with consult sheets and Pediatric Cytogenetics Lab and Developmental Nutrition and Metabolism Laboratory charge slips. Deliver to Suite 3.350, Children's Hospital, UTMB, Galveston, Texas 77555-0359.

4. Preliminary results will be available from Developmental Nutrition and Metabolism Laboratory in 6-8 weeks. A final written report will follow shortly.

5. Any questions should be directed to either Jerome McCombs, Ph.D., 409/772-3466 or David Rassin, Ph.D. 409/772-1139.

INITIAL SAMPLE ACCEPTANCE AND DATA REQUIREMENTS

All samples accepted must have the following information:

1. Labeled sample tube with Patient's name, UH#, or corresponding labeled charge slip number.
2. Three labeled consult sheets with Physician's name, phone number, and reason for referral.
3. Samples will be accepted without consult sheets only if the referring physician is identified and a verbal reason for referral is given.

Time and date the sample is received is printed on the charge slip as illustrated on the following page.

Samples not meeting minimal standards. These are to be called to the laboratory director's attention immediately. At that time a decision will be made by the director as to acceptance/rejection and possible corrective actions are listed below: (**Note: Universal safety precautions in a biological safety cabinet are employed when setting up samples.**)

1. **Amniotic Fluid**
   - A. Bloody--when growth established, flask washed and new medium added.
   - B. <15 ml received--See sheet.
   - C. If doctor did not discard first few cc's, watch for maternal cell contamination. Contact physician and inform him of potential diagnostic difficulties.
   - D. HIV+, hepatitis+, venereal disease+--double gloves, discard waste in separate biohazard bag, pour fluid waste in container with bleach.
2. **Blood**
   - A. Blood in contact with lithium heparin or EDTA--spin out cells and resuspend in medium with sodium heparin right away.

B. Blood syringe on ice--remove from ice immediately.
C. Blood received on Wednesdays:
   1. Set up Thursday for 96-hour culture
   2. Can set up 72-hour synchronized culture on Friday.
      a. Store syringe in refrigerator
D. HIV+, hepatitis+, venereal disease+--see Amniotic Fluid step D above.

Any sample problems or unusual conditions are noted in the patient's chart and reported to laboratory director immediately.

3. **Bone Marrow**
   A. <1 ml received--still set up 2 cultures (direct and overnight)
   B. No visible spicules--proceed but may get less desirable results
   C. HIV+, hepatitis+, venereal disease+--see Amniotic Fluid step D above
   D. BM received on Fridays--do directs
4. **Skin** (morgue specimens, specifically)
   A. If baby in formalin, necrotic skin, dead more than a day: take organ tissue (e.g., heart, lung)
   B. HIV+, hepatitis+, venereal disease+ (baby or its mother): don mask and apron in addition to gloves when taking sample--Refer to Amniotic Fluid step D above

Note: A sheet outlining the unacceptable status of a sample is placed in the patient's chart.

PROTOCOL FOR ACCEPTING < 15 ML AMNIOTIC FLUID

1. Inform lab director that < 15 ml of amniotic fluid was received.
2. Contact referring physician to identify any possible problem that could affect the cell culture and to confirm that the physician is aware of our amniotic fluid requirement of 20-33 cc.
3. Initiate two flasks (25 cm).
4. Perform standard analysis of 20 cells.
5. If the standard analysis reveals a 46,XX, count an additional 50 cells with fluorescence (Q-bands).
6. State in the report (if female is identified) that due to the limited sample the possibility exists for maternal cell contamination and this cannot be excluded.

GUIDELINES FOR LABELING PATIENT SAMPLE TUBES, SLIDES, CAPTURED IMAGES, AND PHOTOGRAPHS

1. Samples are initiated following standard procedures in the protocol manual.
2. Only one patient is initiated (cultures started in biosafety cabinet) at a time.
3. Place on each flask a label (tape) containing:
   A. Name
   B. Laboratory #
   C. Date initiated
   D. Type medium
   E. + or - EB
4. When transferring sample to conical centrifuge tube, merely peel tape from flask and place on centrifuge tube.
5. Color code pipets that are used with each sample to match sample tape.
6. When slides are made, each slide is to be labeled as it is made. Label will include:
   A. Name
   B. Laboratory #
   C. Type medium
   D. + or - EB/Synch
7. Slides are to be prepared on one patient at a time.
8. It has been out policy to retain all slides, negatives, and prints permanently on all cases, normal and abnormal. Note: In APRIL, 1996, a PSI imaging system completely replaced our darkroom facility. CAPTURED IMAGES have legends containing name, number, date and slide # and coordinates. All karyotypes generated continue to show patient name, number, karyotype designation, and karyotype date.

REQUEST FOR CONSULTATION

FORWARD WRITTEN REPORT TO:

Dr. _____

Address: _____

_____

_____

☐ **IN ADDITION TO WRITTEN REPORT, PLEASE CALL EXT / BEEPER# BELOW.**

TO: PHYSICIAN OR SERVICE

Reason for Requesting Consultation – This request is: ☐ **URGENT** ☐ **ROUTINE**

Signature:
(Physician) Ext.# Beeper: Date:

REPORT: _____

I have examined the patient and reviewed the medical record.

Signature/Title: _____ Ext. # _____ Beeper: _____

Service: _____ Date: _____

Approved: _____

DATA ENTRY AND CODING

All samples are entered sequentially into the Patient Log Book located in the Microscope Room.

Data to be entered:

Lab #[sequential # followed by suffix indicating sample type (BL-blood; AF- amniotic fluid; SK-skin; BM-bone marrow)]
Date Received
Patient Name
UH Number
DOB
Race
Service
Pay Class
Charge Slip Sent
Referring Physician
Indication
Date Completed
ISCN Diagnosis
Additional Information (e.g., AF, AFP results, etc.)

Patient/sample information entered on daily tissue culture log sheets (ring binder in microscope room), AF log sheets filed in patient's folder when study is completed.

The following table lists indication for cytogenetic studies and possible chromosomal causes. This is merely a general guideline and does not preclude a complete analysis.

Approved: _____

REASON FOR REFERRAL

Problem	Possible Anomalies
Ambiguous Genitalia	X and Y - ACCBI
Amenorrhea	X
Aniridia	11p13
Azoospermia	X and Y - ACCBI
Behavior Problems	X and Y - ACCBI
Cat-Eye Syndrome	22pter-q11
Cleft Lip and Palate	ACCBI
Congenital Heart Disease	ACCBI
Cornelia-de-Lange	tri 3q or 13q
Developmental Delay	ACCBI
Di George	22q11
Epilepsy	ACCBI
Exomphalos	18-ACCBI
Failure to Thrive	ACCBI
Floppy Baby	15q12,+21 - ACCBI
Gynecomastia	X or Y
Hypospadia	del of ACCBI
Infertility	X or Y, Translocation-ACCBI
Langer-Giedions Syndrome	8q22-24
Macro-orchidism	fra(X)
Mental Retardation	fra(X)-ACCBI
Microcephaly	4p, 5p, 13q-,18-ACCBI
Multiple Congenital Anomalies	ACCBI
Odd Facies	ACCBI
Prader-Willi	15q11-12
Recurrent Miscarriages	ACCBI
Retinoblastoma	13q14
Rocker Bottom Feet	13 or 18
Small Stature	X
Seizures	4p, 9p-, ACCBI
Tall	X or Y
Wilms Tumor	11p13

* Any Chromosome Could Be Involved